(Response) Detention orders will be dated and will include the period of detention. Therefore, anyone can determine the expiration date of that detention order. We could attempt to predict at the time we issued detention orders whether we might terminate those detention orders or move to seizure actions before the expiration date, or whether we might need to extend the detentions for an additional 10 calendar days. We could then revise detention orders as our assessment changed over time. However, that would substantially increase our enforcement costs. The benefit of this action is that the recipient of the detention order might be in a better position to plan any appeals or subsequent disposition of the food.

(Comment 137) One comment suggests that we provide information on the analyses and methods that we use to analyze food that we detain administratively.

(Response) As we discussed earlier in this preamble, information on the analyses and methods that we use to analyze food is available on FDA's Web site at http://www.fda.gov.

(Comment 138) Some comments suggest that we provide the owner a sample of the detained food to allow them to conduct their own tests.

(Response) With respect to providing counter-samples, section 702(b) of the FD&C Act describes FDA's responsibility to provide a part of an official sample of food to certain

individuals, when a sample is collected for analysis under the FD&C Act. Section 702(b) of the FD&C Act requires the Secretary to, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this section as he finds necessary for the proper administration of the provisions of the FD&C Act. Therefore, when our own collection of a sample requires us to provide a part of that sample to the owners, we will do so. However, when we are not required to provide a part of that sample to the owners, we will not do so. If we do not take a sample, then we will also not provide owners with a sample. Always providing owners with a sample when we collect a sample would increase our enforcement costs but might reduce costs in some situations by allowing us to terminate some detention orders. Providing owners with samples in situations in which we do not take samples for our own purposes would increase our enforcement costs and would have a minimal impact on other costs. In particular, if we did not rely on testing to establish our case for an administrative detention, then providing owners with samples would probably likely have little impact on the appeal.

(Comment 139) One comment suggests that we allow owners of detained food to have access to the written approval granted by the authorized FDA representative to ensure that the owners have all of the necessary information to address any potential concerns.

(Response) The owner of detained food can obtain a copy of the written approval granted by the authorized FDA representative under FOIA, after we have removed any information that is protected from disclosure to the public. However, owners might not be able to get such a copy quickly enough to use during their appeal. Providing owners of food that we detain administratively faster access to written approvals granted by authorized FDA representatives would increase our enforcement costs and would probably generate no or minimal benefits. Allowing owners access to written approvals would allow them to confirm that administrative detention orders were properly approved. However, owners do not need access to those documents to raise this issue in an appeal. Therefore, making this change would probably not increase net benefits.

(Comment 140) Some comments were concerned about the information that we would provide to the public concerning administrative detentions. Some comments suggest that we should only make information on administrative detentions public if it were necessary to protect public health. These comments suggest

that we ensure that any information that we release to the public on administrative detentions is accurate and that we transmit such information in a clear, unemotional, and factual manner without unduly or inaccurately raising public concern.

(Response) We do not currently plan to publicize administrative detentions unless it is necessary to protect the public health. However, members of the public can request information on administrative detentions under the Freedom of Information Act. If we found it necessary to inform the public for public health reasons, then we would ensure that the information that we provided to the public is accurate and that we transmitted it in an appropriate manner that would not unduly or inaccurately raise public concern.

(Comment 141) One comment suggests that we revise the rule to require that Regional FDA Directors or more senior level officials approve administrative detentions because of the serious cost implications involved.

(Response) This revision would increase our enforcement costs by reducing the number of eligible authorizing officials and by increasing the payroll and opportunity costs associated with approving detentions. The potential benefit would be a reduction in the number of administrative detentions that we later terminate because of a successful appeal or because we later determined that they involved food that did not pose a

serious adverse health consequences or death to humans or animals threat. We have no information establishing that this benefit would occur.

(Comment 142) One comment notes that we proposed that government employees commissioned or deputized by FDA may order a detention. This comment argues that we should revise the rule to allow only FDA employees to order and administer detentions because that would aid in the credibility of the process.

(Response) Revising the rule to allow only FDA employees to order and administer administrative detentions would increase our enforcement costs. If this revision aided the credibility of the process, then it might reduce the possibility of legal complaints and might also reduce the number of unjustified appeals, both of which would decrease costs. However, the comment did not provide information establishing that this effect would occur.

e. Compensation. (Comment 143) Many comments argue that we should compensate firms for costs associated with administrative detentions that we later terminate because of a successful appeal or because we later determined that it involved food that did not pose a threat of serious adverse health consequences or death to humans or animals. One comment suggested that we should at least compensate firms for some percentage of the costs, because it would provide us with an

incentive to avoid excessive use of administrative detentions. One comment suggests that we compensate farmers for the costs of administrative detentions.

(Response) Neither the FD&C Act nor the Bioterrorism Act provide FDA with authority to compensate firms for costs associated with administrative detention. Even if FDA had such authority, if we compensated firms for costs associated with administrative detentions, then we would shift the burden of those costs from the affected firms to taxpayers in general. This is primarily a distributional issue that goes beyond the scope of this analysis.

f. Labeling and marking. (Comment 144) One comment suggests that we add the name of the authorized FDA representative to the information that we put on the tags or labels that we affix to food that is detained administratively.

(Response) Including the name of the authorized FDA representative on the tags or labels that we affix to detained food would increase our enforcement costs slightly, but would not affect other costs or benefits. We will provide information on how to appeal or obtain more information on administrative detentions in the detention order. It is possible that someone might have access to the tag or label but not the detention order, so there could be some benefit to adding a contact name to the tag or label. However, this situation is probably

unlikely. Most people who may be interested in appealing an administrative detention will probably be able to obtain a copy of the detention order. Therefore, this change would probably not increase net benefits.

g. Transportation. (Comment 145) One comment suggests that we define and make available for public comment the conditions that we believe would warrant transporting food that is detained administratively to secure storage facilities.

(Response) Defining the conditions that would warrant transporting food to secure storage facilities would increase the cost for us to develop this rule because we would need to consider and evaluate every scenario that might require transportation. In addition, if we wrote these conditions into the rule, then we might need to revise the rule as we gain experience with administrative detentions. Also, if we wrote these conditions into the rule, and we failed to anticipate all situations in which transportation was appropriate, then we might need to resort to relatively inefficient and expensive alternatives. The benefit of defining the conditions warranting transporting food to secure storage facilities is that it would prevent inconsistent decisions about transporting food to secure storage and would allow the public to provide input on when transportation would be most worthwhile.

(Comment 146) One comment requests that we change the rule to include some provisions regarding appropriate transportation conditions, such as keeping refrigerated foods under 40 degrees F and frozen foods under -4 degrees F. One comment notes that we did not define the mode of transport in the case of limited conditional release and argues that we should require that the mode of transport not introduce any condition or substance that would adulterate or otherwise deleteriously impact the quality of the detained food.

(Response) We will normally maintain existing storage conditions during transportation to secure storage facilities. If the owner wishes, he or she can request that we maintain different storage conditions or request modification of a detention order. In the case of a request to modify the detention order, the party requesting modification of the detention order would determine the conditions during transportation.

(Comment 147) One comment requests that we revise the rule to require that the owner, purchaser, importer, or consignee, pay the transportation costs of food that is detained administratively. This comment notes that this would be consistent with the rule on prior notice (part 1, subpart I). The comment argues that a trucking company should not have to

pay transportation costs because they have no control over the quality or safety of what a shipper loads into the trailer.

(Response) Resolving the issue of who should pay for transportation is a distributional issue that is beyond the scope of this analysis.

h. Storage facilities. (Comment 148) Some comments state that we should guarantee that we will have enough secure storage facilities with appropriate storage conditions for products that we detain administratively.

(Response) Guaranteeing that we have appropriate secure storage facilities for all food that we might detain administratively could generate significant costs because of the uncertainty over the number and location of detentions and whether there is a need to transport detained food to secure storage. It would generate minimal benefits because, in many cases, it may be cheaper and more or equally effective to secure detained food in place. Therefore, this change would probably increase the net costs of this rule.

(Comment 149) One comment notes that our decision to move food to secure storage, and our selection of appropriate storage facilities, could have a significant impact on the storage costs that the owners of detained food would face. The comment suggests that we ensure that such storage facilities impose the minimum cost necessary to achieve the objectives of the

detention, with respect to both security and food storage conditions such as refrigeration.

(Response) Ensuring that storage facilities impose the minimum cost necessary to achieve the objectives of administrative detentions would increase our enforcement costs by requiring us to spend time shopping for storage facilities. This would also increase the time we need to implement administrative detentions, which might reduce benefits. The benefit of ensuring that we use the lowest cost storage facility is that it would give us an incentive to reduce storage costs to the lowest level possible. This benefit would probably be small. When we use commercial storage facilities, the price difference between the facility that we choose and the lowest cost appropriate storage facility would probably be relatively modest due to price competition in the commercial storage market. The same considerations apply to any conveyances that we use to move food that we detain administratively to secure storage facilities.

(Comment 150) One comment suggests that we require the person holding legal title to the food to bear the cost of storing food that is detained administratively. This person might be a shipper, the consignee, or a food broker. One comment requests that we revise the rule to require that the owner, purchaser, importer, or consignee pay any storage costs.

This comment notes that this would be consistent with the rule on prior notice (part 1, subpart I). The comment argues that a trucking company should not pay storage costs because they have no control over the quality or safety of the food a shipper loads into the trailer.

(Response) The issue of who should pay for storing food that is detained administratively is a distributional issue that is beyond the scope of this analysis.

(Comment 151) One comment suggests that we provide records of storage conditions during detention to owners of detained food, upon request.

(Response) Providing records of storage conditions to owners upon request would increase our enforcement costs slightly. This revision would probably have a minimal impact on benefits or distributional effects because we will allow owners to verify storage conditions, except where security concerns prevent it.

(Comment 152) Some comments argue that owners should be able to inform us about the optimal storage conditions for food that we detain administratively and that they should be able to submit a claim against us if we do not follow their recommendations. One comment requests that we revise the rule to include some provisions regarding appropriate storage, such as keeping refrigerated foods under 40 degrees F and frozen

foods under -4 degrees F. One comment requests that we commit to holding refrigerated and frozen food at the same refrigerated and frozen temperatures and conditions that are found in U.S. commercial cold storage facilities. This comment also suggests that we allow owners, operators, or agents to request that we freeze detained fresh products that are or are likely to be, detained for 4 or more days. One comment recommends that we develop procedures regarding administrative detention for perishable foods, including a specific process that would ensure the preservation of such foods until we resolve the administrative detention.

(Response) We will normally maintain existing storage conditions during administrative detentions. If the owner wishes, he or she can request that we hold the food under different conditions or request modification of the detention order. We would accede to one or the other of these requests except where security concerns prevent it. We know of no process that would ensure the preservation of perishable foods during the detention period.

i. Off loading from conveyance/partial loads. (Comment 153) One comment suggests that we reduce the potential economic effects of detaining large oceangoing vessels by taking one of the following actions: (1) Not detaining products on vessels at ports without first allowing the product to be offloaded to

secure storage; (2) specifically providing for the removal of products from vessels to secure storage in the detention order; or (3) specifying that moving detained product from the vessel qualifies as a basis for a conditional release, thus permitting the movement of detained product to secure storage. One comment notes that ships carrying bulk vegetable oils hold the oil in individual parcel tanks. This comment notes that a ship might transport many parcel tanks of various types of vegetable oil to many buyers in different locations. The comment notes that a single ship could carry more than 50 separate parcel tanks. This comment argues that if we receive intelligence on the potential contamination of a particular parcel tank, then we should remove that parcel tank to secure shore storage and allow the ship to proceed with deliveries of the remaining parcel tanks. One comment argues that removal of a product from a conveyance to secure storage should be one of the bases on which a claimant may seek a limited conditional release. Another comment suggests that we revise the rule to indicate that, if we detain food on a truck, then we will issue an order to the trucking company to deliver the food to either the consignee or to a secure location.

(Response) Owners and operators of conveyances may request modification of a detention order to move food from a conveyance to other storage. We generally would accede to such requests

unless they generated health risks or raised security concerns. If we determine that only a portion of a cargo of food products meets the criteria for administrative detention, the food or other items that can be readily segregated and not detained can be segregated and moved. In the analysis of the proposed rule, we noted that our experience with other enforcements actions is that we would not cause significant delays in the delivery of food that is packed with food that we detain administratively. These comments did not provide information that would require us to revise that assessment.

(Comment 154) One comment requests that we develop a process by which we would reseal a tank truck load that we determined did not present a problem with an FDA seal and indicate the resealing on an official FDA document. The comment notes that receivers might still reject the load, but that they would be less likely to reject it under these conditions.

(Response) We will reseal a tank truck load that did not present a problem with an FDA seal, but we will not provide an official FDA document to that effect. Providing an official FDA document would increase our enforcement costs slightly. It is possible that such a document might reduce costs by encouraging receivers to accept resealed loads. However, in the discussion of this issue under Option One, we concluded that market forces would probably minimize unnecessary rejections of resealed

loads. The comment did not provide information that would allow us to quantify this practice or to estimate the effect of an official FDA document on reducing it.

j. Timeframes. (Comment 155) One comment argues that if we needed to use any of the additional 10 calendar days beyond the initial 20-calendar day period, then we should inform the owner of the food of this additional time requirement, the reasons we need the additional time, and the actual time period that we will require, up to the maximum of 10 calendar days.

(Response) The initial detention order will include an expiration date based on the initial 20-calendar day period. In addition, FDA notes that under § 1.379(a), FDA can order detention of the article of food for 30 calendar days in the original detention order, if we know from the outset that 30 rather than 20 calendar days will be needed to institute a seizure or injunction against the detained article of food.

If we needed to use the additional 10 calendar days, then we would issue a new detention order with a new period of detention based on that time period. Basing the period of detention of the new detention order on our estimate of the portion of the maximum period of 10 calendar days that we think we might require would increase our enforcement costs because it would require us to develop a model to estimate the time required, and we might need to prepare additional detention

orders if we underestimated the time that we needed. The benefit of this change is that it would allow owners to make plans based on our current assessment of the time that we require. This benefit would probably be minimal because we will inform owners as quickly as possible if we terminate a detention order before the detention period has expired. Providing owners with the reasons we need additional time would also increase our enforcement costs. The benefit of providing this information to owners is unclear. Any benefit would probably be minimal because we intend to proceed as quickly as possible with activities pertaining to food that we detain administratively. Therefore, these changes would probably not increase net benefits.

k. Appeal hearings. (Comment 156) One comment suggests that we start the timeframe for appeal when we notify someone who is authorized to file an appeal. One comment requests that we revise the rule to give the shipper the right to appeal. One comment wonders whether everyone with a commercial interest in the food, such as an importer, could file an appeal. One comment suggests that we revise the rule to allow the owner to designate someone else to appeal a detention order, such as a lawyer or a food engineer, in case the owner felt that he or she did not have the proper skills to do so.

(Response) Any person who would be entitled to be a claimant for the article of food, if seized under section 304(a) of the FD&C Act, may appeal an administrative detention. The local rules of the Federal court district in which a seizure or administrative detention occurs set forth the procedures by which a party establishes entitlement to be a claimant, or files a statement of interest under the revised Supplemental Rule C(6) of the "Federal Rules of Civil Procedure," and a determination of whether a party has a sufficient interest in the goods is made on a case-by-case basis.

As required in § 1.392, we will provide a copy of the detention order to the owner, operator or agent in charge of the place where the food is located and to the owner of the food, if the owner's identity can be determined readily. Examples of steps FDA will take to determine the identity of the owner of a detained article of food include examining any readily available bills of lading or invoices for the article of food and asking the owner, operator, or agent in charge of the place where the detained article of food is located for any information he or she may have regarding the identity of the owner of the article of food. Though FDA will make reasonable efforts to identify the owner of the food and to notify that person of the administrative detention while there is still time to file an

appeal, it may not always be possible for us to identify the owner of the food.

Other parties with a commercial interest in the food, including importers and shippers, would generally be able to file an appeal. Owners or other parties who wished to appeal an administrative detention may choose to have other parties, such as lawyers and food engineers, represent them for purposes of the appeal, once the appeal is filed in the owner's name.

Changing the rule to ensure that at least one party that is able to file an appeal has time to file an appeal after they learn of the detention, or that everyone with a financial interest in the food has time to appeal a detention, or that owners or other parties who wished to appeal a detention have an opportunity to arrange for other parties to represent them, would increase our enforcement costs. It would also probably increase the number of appeals, which would further increase our enforcement costs but also increase benefits by the mechanism we described earlier. These changes might also address some distributional concerns.

The revised §§ 1.403(h) and 1.405(a) require the presiding officer to issue a report, including a proposed decision confirming or revoking the detention order, by noon on the fifth calendar day, while giving the participant 4 hours to submit changes and corrections before a final decision is issued.

These changes will increase the probability that we will correctly terminate a detention order when the food does not present a risk, but will also increase our enforcement costs by some amount.

(Comment 157) Some comments argue that we should guarantee the right to a hearing. One comment suggests that we establish a national detention approval board to ensure uniform application of the regulation. The comment argues that establishing such a board would allow us to avoid costly errors and delays.

(Response) As we indicated earlier, we would only grant a request for a hearing after an appeal is filed, if a firm submitted material that raised a genuine and substantial issue of fact. Guaranteeing the right to an appeal hearing would increase our enforcement costs. It might also increase benefits, because in some cases, our initial assessment of whether a firm submitted material that raised a genuine and substantial issue of fact might be incorrect. In that case, we might fail to terminate a detention that we would otherwise have terminated. This effect would probably be minimal because, as stated earlier, we will probably grant a hearing in most cases in which a hearing is requested.

Establishing a national detention approval board would increase our enforcement costs. It might reduce the costs of

this rule by allowing us to avoid costly errors and delays. However, the comment did not provide evidence that this effect would occur.

(Comment 158) Some comments request that we provide additional guidance on how to file an appeal, addressing such issues as whether we require all appeals to include certain basic information. One comment suggests that we run workshops for local trainers and prepare slide and video presentations, online training manuals, and explanatory leaflets on how to appeal administrative detentions. One comment suggests that we describe appeal procedures and deadlines in the detention order. The comment suggests that we include the following information in the detention order: The claimant has a right to appeal the order; the appeal must be submitted in writing to the appropriate (and identified) FDA District Director, the number of days the claimant has to file the appeal and request a hearing, and the date by which such an appeal and request must be made.

(Response) We will provide information on how to appeal administrative detentions in the detention orders. As stated previously, we also plan extensive outreach materials, including explanatory materials, such as slide presentations, a satellite downlink meeting, and fact sheets, to explain the requirements of the final rule, similar to what we did for the proposed rule.

Providing other information and guidance would increase our enforcement costs. It would probably have a minimal impact on other costs and distributional effects because anyone wishing to file an appeal could learn what to do from these materials.

(Comment 159) Some comments suggest that we revise the rule to require that the official presiding at an informal hearing be senior to the official who approved the detention order. They argue that presiding officials may be less likely to terminate detention orders if FDA employees senior to those presiding officials authorized those orders.

(Response) Revising the rule as this comment suggests might increase the likelihood that we would terminate some administrative detention orders during the appeal process for the reasons this comment suggests. However, we have insufficient information to establish that this effect would take place. This revision would increase our enforcement costs by reducing the pool of employees that would be eligible to either authorize administrative detentions or to preside at appeals hearings.

(Comment 160) One comment suggests that appeals hearings should include participation or attendance by third parties.
(Response) Including a third party in appeals hearings would increase the costs associated with those hearings. The comment did not explain the mechanism by which the presence of a third

party would reduce costs or increase benefits. We note, however, that hearings generally are open to anyone who wishes to attend as a nonparticipant, unless classified or confidential information (e.g., information exempt from disclosure under applicable laws) is being discussed.

1. Summary. Table 5 of this document summarizes the range of costs and benefits for the five options that we have considered. We have indicated that we cannot determine the effects of many of the suggested revisions that we discussed under Option Five. However, we have insufficient information to establish that any of those revisions would increase net benefits.

Table 5.--Summary of Annual Costs and Benefits

Option	Costs (in Millions	Benefits
One--Transportation and Perishable Foods as Proposed	$0 to $50	> $0
Two--Perishable Foods Alternatives	$0 to $42	> $0 , But < Option One
Three--No Transportation, But One Additional Guard	$0 to $56	> $0

Four--Limited to the Bioterrorism Act	>$0 to >$50	> $0, But ≤ Option One
Five--Revise in Other Ways	N/A	N/A

B. Final Regulatory Flexibility Analysis

We have examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities. We find that this final rule would not have a significant economic impact on a substantial number of small entities.

(Comment 161) In the analysis of the proposed rule, we requested comments on the impact of the proposed rule on small entities. The only comment we received on this issue noted that most firms making indirect food contact color pigments that firms may use in the manufacture of food packaging are small businesses.

(Response) This comment is consistent with the analysis in the proposed rule. Therefore, we have not revised the analysis that we presented in the proposed rule.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires cost-benefit and other analyses before any rulemaking if the rule would include a ''* * *Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' The current inflation-adjusted statutory threshold is $112.3 million per year. We have estimated that the total cost of the proposed rule would be no more than $50 million per year. Therefore, we have determined that this final rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

D. Small Business Regulatory Enforcement Fairness Act (SBREFA) Major Rule

SBREFA (Public Law 104-121) defines a major rule for the purpose of congressional review as having caused, or being likely to cause, one or more of the following: An annual effect on the economy of $100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance

with SBREFA, OMB has determined that this final rule is not a major rule for the purpose of congressional review.

VII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

We conclude that these information collection provisions are exempt from OMB review under 44 U.S.C. 18(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. The regulations in 5 CFR 1320(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the decision to detain an article of food.

VIII. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the

human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency concludes that the final rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

X. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.

1. Holcomb, Harry, Area officials have adapted a tracking system to watch over U.S. ships in an age of terrorism, accessed on the Internet at http://www.philly.com/mld/inquirer/5369951.htm, accessed on September 16, 2003.

2. AAA Environmental Industry, Inc., Cost Proposal, Schedule of Standard Rates Effective July 1, 2002, available on the Internet at http://vendornet.state.wi.us/vendornet/wais/bulldocs/1431_4.doc, accessed on September 16, 2003.

3. National Compensation Survey: Occupational Wages in the United States, July 2002. U.S. Department of Labor, Bureau of Labor Statistics, June 2003. Available on the Internet at http://stats.bls.gov/ncs/ocs/sp/ncbl0539.pdf, accessed on September 16, 2003.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 16

Administrative practice and procedure.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1, 10, and 16 are amended as follows:

PART 1--GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 continues to read as follows:

AUTHORITY: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Subpart K is added to part 1 to read as follows:

Subpart K--Administrative Detention of Food for Human or Animal Consumption

General Provisions

Sec.

Subpart K--Administrative Detention of Food for Human or Animal Consumption

General Provisions

§ 1.377 What definitions apply to this subpart?

The definitions of terms that appear in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart. In addition, for the purposes of this subpart:

Act means the Federal Food, Drug, and Cosmetic Act.

Authorized FDA representative means an FDA District Director in whose district the article of food involved is located or an FDA official senior to such director.

Calendar day means every day shown on the calendar.

Food has the meaning given in section 201(f) of the act (21 U.S.C. 321(f)). Examples of food include, but are not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients, infant formula, beverages, including alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy, and canned foods.

Perishable food means food that is not heat-treated; not frozen; and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 calendar days under normal shipping and storage conditions.

We means the U.S. Food and Drug Administration (FDA).

Working day means any day from Monday through Friday, excluding Federal holidays.

You means any person who received the detention order or that person's representative.

§ 1.378 What criteria does FDA use to order a detention?

An officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the act if the officer or qualified employee has credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals.

§ 1.379 How long may FDA detain an article of food?

(a) FDA may detain an article of food for a reasonable period that may not exceed 20 calendar days after the detention order is issued. However, an article may be detained for 10 additional calendar days if a greater period of time is required to institute a seizure or injunction action. The authorized FDA representative may approve the additional 10-calendar day detention period at the time the detention order is issued, or at any time within the 20-calendar day period by amending the detention order.

(b) The entire detention period may not exceed 30 calendar days.

(c) An authorized FDA representative may, in accordance with § 1.384, terminate a detention order before the expiration of the detention period.

§ 1.380 Where and under what conditions must the detained article of food be held?

(a) You must hold the detained article of food in the location and under the conditions specified by FDA in the detention order.

(b) If FDA determines that removal to a secure facility is appropriate, the article of food must be removed to a secure facility. A detained article of food remains under detention before, during, and after movement to a secure facility. FDA will also state in the detention order any conditions of transportation applicable to the detained article.

(c) If FDA directs you to move the detained article of food to a secure facility, you must receive a modification of the detention order under § 1.381(c) before you move the detained article of food to a secure facility.

(d) You must ensure that any required tags or labels under § 1.382 accompany the detained article during and after movement. The tags or labels must remain with the article of food until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the authorized FDA representative.

(e) The movement of an article of food in violation of a detention order issued under § 1.393 is a prohibited act under section 301 of the act (21 U.S.C. 331).

§ 1.381 May a detained article of food be delivered or transferred to another location?

+ to another entity/ per Brad Bookout OK w/ K Smith 5-27-09

(a) An article of food subject to a detention order under this subpart may not be delivered under the execution of a bond. Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), while any article of food is subject to a detention order under section 304(h) of the act (21 U.S.C. 334(h)), it may not be delivered to any of its importers, owners, or consignees. This section does not preclude movement at FDA's direction of imported food to a secure facility under an appropriate Customs' bond when that bond is required by Customs' law and regulation.

(b) Except as provided in paragraph (c) of this section, no person may transfer a detained article of food within or from the place where it has been ordered detained, or from the place to which it was removed, until an authorized FDA representative releases the article of food under § 1.384 or the detention period expires under § 1.379, whichever occurs first.

(c) The authorized FDA representative may approve, in writing, a request to modify a detention order to permit movement of a detained article of food for any of the following purposes:

(1) To destroy the article of food,

(2) To move the detained article of food to a secure facility under the terms of a detention order,

(3) To maintain or preserve the integrity or quality of the article of food, or

(4) For any other purpose that the authorized FDA representative believes is appropriate in the case.

(d) You must submit your request for modification of the detention order in writing to the authorized FDA representative who approved the detention order. You must state in your request the reasons for movement; the exact address of and location in the new facility (or the new location within the same facility) where the detained article of food will be transferred; an explanation of how the new address and location will be secure, if FDA has directed that the article be detained in a secure facility; and how the article will be held under any applicable conditions described in the detention order. If you are requesting modification of a detention order for the purpose of destroying the detained article of food, you also must submit a verified statement identifying the ownership or proprietary interest you have in the detained article of food, in accordance with Supplemental Rule C to the "Federal Rules of Civil Procedure."

(e) If FDA approves a request for modification of a detention order, the article may be transferred but remains under detention before, during, and after the transfer. FDA will state any conditions of transportation applicable to the detained article. You may not transfer a detained article of food without FDA supervision unless FDA has declined in writing to supervise the transfer. If FDA has declined in writing to supervise the transfer of a detained article, you must immediately notify in writing the authorized FDA representative who approved the modification of the detention order that the article of food has reached its new location, and the specific location of the detained article within the new location. Such written notification may be in the form of a fax, e-mail, or other form as agreed to by the authorized FDA representative.

(f) You must ensure that any required tags or labels under § 1.382 accompany the detained article during and after movement. The tags or labels must remain with the article of food until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the authorized FDA representative who approves the modification of a detention order under this section.

(g) The transfer of an article of food in violation of a detention order issued under § 1.393 is a prohibited act under section 301 of the act.

§ 1.382 What labeling or marking requirements apply to a detained article of food?

The officer or qualified employee of FDA issuing a detention order under § 1.393 may label or mark the detained article of food with official FDA tags or labels that include the following information:

(a) A statement that the article of food is detained by FDA in accordance with section 304(h) of the act;

(b) A statement that the article of food must not be consumed, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative;

(c) A statement that the violation of a detention order or the removal or alteration of the tag or label is a prohibited act, punishable by fine or imprisonment or both; and

(d) The detention order number, the date and hour of the detention order, the detention period, and the name of the officer or qualified employee of FDA who issued the detention order.

§ 1.383 What expedited procedures apply when FDA initiates a seizure action against a detained perishable food?

If FDA initiates a seizure action under section 304(a) of the act against a perishable food subject to a detention order under this subpart, FDA will send the seizure recommendation to

the Department of Justice (DOJ) within 4 calendar days after the detention order is issued, unless extenuating circumstances exist. If the fourth calendar day is not a working day, FDA will advise the DOJ of its plans to recommend a seizure action on the last working day before the fourth calendar day and send the recommendation as soon as practicable on the first working day that follows. For purposes of this section, an extenuating circumstance includes, but is not limited to, instances when the results of confirmatory testing or other evidentiary development requires more than 4 calendar days to complete.

§ 1.384 When does a detention order terminate?

If FDA terminates a detention order or the detention period expires, an authorized FDA representative will issue a detention termination notice releasing the article of food to any person who received the detention order or that person's representative and will remove, or authorize in writing the removal of, the required labels or tags. If FDA fails to issue a detention termination notice and the detention period expires, the detention is deemed to be terminated.

How Does FDA Order a Detention?

§ 1.391 Who approves a detention order?

An authorized FDA representative, i.e., the FDA District Director in whose district the article of food involved is located or an FDA official senior to such director, must approve

a detention order. If prior written approval is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible.

§ 1.392 Who receives a copy of the detention order?

(a) FDA must issue the detention order to the owner, operator, or agent in charge of the place where the article of food is located. If the owner of the article of food is different from the owner, operator, or agent in charge of the place where the article is detained, FDA must provide a copy of the detention order to the owner of the article of food if the owner's identity can be determined readily.

(b) If FDA issues a detention order for an article of food located in a vehicle or other carrier used to transport the detained article of food, FDA also must provide a copy of the detention order to the shipper of record and the owner and operator of the vehicle or other carrier, if their identities can be determined readily.

§ 1.393 What information must FDA include in the detention order?

(a) FDA must issue the detention order in writing, in the form of a detention notice, signed and dated by the officer or qualified employee of FDA who has credible evidence or information indicating that such article of food presents a

threat of serious adverse health consequences or death to humans or animals.

(b) The detention order must include the following information:

(1) The detention order number;

(2) The date and hour of the detention order;

(3) Identification of the detained article of food;

(4) The period of the detention;

(5) A statement that the article of food identified in the order is detained for the period shown;

(6) A brief, general statement of the reasons for the detention;

(7) The address and location where the article of food is to be detained and the appropriate storage conditions;

(8) Any applicable conditions of transportation of the detained article of food;

(9) A statement that the article of food is not to be consumed, moved, altered, or tampered with in any manner during the detention period, unless the detention order is first modified under § 1.381(c);

(10) The text of section 304(h) of the act and §§ 1.401 and 1.402;

(11) A statement that any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing

under part 16 of this chapter, with certain exceptions described in § 1.403;

(12) The mailing address, telephone number, e-mail address, and fax number of the FDA district office and the name of the FDA District Director in whose district the detained article of food is located;

(13) A statement indicating the manner in which approval of the detention order was obtained, i.e., verbally or in writing; and

(14) The name and the title of the authorized FDA representative who approved the detention order.

What is the Appeal Process for a Detention Order?

§ 1.401 Who is entitled to appeal?

Any person who would be entitled to be a claimant for the article of food, if seized under section 304(a) of the act, may appeal a detention order as specified in § 1.402. Procedures for establishing entitlement to be a claimant for purposes of section 304(a) of the act are governed by Supplemental Rule C to the "Federal Rules of Civil Procedure."

§ 1.402 What are the requirements for submitting an appeal?

(a) If you want to appeal a detention order, you must submit your appeal in writing to the FDA District Director, in whose district the detained article of food is located, at the mailing address, e-mail address, or fax number identified in the

detention order according to the following applicable timeframes:

(1) Perishable food: If the detained article is a perishable food, as defined in § 1.377, you must file an appeal within 2 calendar days of receipt of the detention order.

(2) Nonperishable food: If the detained article is not a perishable food, as defined in § 1.377, you must file a notice of an intent to request a hearing within 4 calendar days of receipt of the detention order. If the notice of intent is not filed within 4 calendar days, you will not be granted a hearing. If you have not filed a timely notice of intent to request a hearing, you may file an appeal without a hearing request. Whether or not it includes a request for hearing, your appeal must be filed within 10 calendar days of receipt of the detention order.

(b) Your request for appeal must include a verified statement identifying your ownership or proprietary interest in the detained article of food, in accordance with Supplemental Rule C to the "Federal Rules of Civil Procedure."

(c) The process for the appeal of a detention order under this section terminates if FDA institutes either a seizure action under section 304(a) of the act or an injunction under section 302 of the act (21 U.S.C. 276) regarding the article of food involved in the detention order.

(d) As part of the appeals process, you may request an informal hearing. Your request for a hearing must be in writing and must be included in your request for an appeal specified in paragraph (a) of this section. If you request an informal hearing, and FDA grants your request, the hearing will be held within 2 calendar days after the date the appeal is filed.

§ 1.403 What requirements apply to an informal hearing?

If FDA grants a request for an informal hearing on an appeal of a detention order, FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(a) The detention order under § 1.393, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter;

(b) A request for a hearing under this section must be addressed to the FDA District Director in whose district the article of food involved is located;

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(c) The provision in § 16.22(b) of this chapter, providing that a person not be given less than 3 working days after receipt of notice to request a hearing, does not apply to a hearing under this subpart;

(d) The provision in § 16.24(e) of this chapter, stating that a hearing may not be required to be held at a time less

than 2 working days after receipt of the request for a hearing, does not apply to a hearing under this subpart;

(e) Section 1.406, rather than § 16.24(f) of this chapter, describes the statement that will be provided to an appellant where a detention order is based on classified information;

(f) Section 1.404, rather than § 16.42(a) of this chapter, describes the FDA employees, e.g., Regional Food and Drug Directors or other officials senior to a District Director, who preside at hearings under this subpart;

(g) The presiding officer may require that a hearing conducted under this section be completed within 1 calendar day, as appropriate;

(h) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 4 hours of issuance of the report. The presiding officer will then issue the final agency decision.

(i) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 1.403(h) are part of the administrative record.

(j) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final agency decision.

(k) If FDA grants a request for an informal hearing on an appeal of a detention order, the hearing must be conducted as a regulatory hearing pursuant to regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 1.403(i) constitutes the exclusive record for the presiding officer's final decision on an administrative detention. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 1.404 Who serves as the presiding officer for an appeal, and for an informal hearing?

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 1.405 When does FDA have to issue a decision on an appeal?

(a) The presiding officer must issue a written report that includes a proposed decision confirming or revoking the detention by noon on the fifth calendar day after the appeal is filed; after your 4 hour opportunity for submitting comments under § 1.403(h), the presiding officer must issue a final decision within the 5-calendar day period after the appeal is filed. If FDA either fails to provide you with an opportunity to request an informal hearing, or fails to confirm or terminate the detention order within the 5-calendar day period, the detention order is deemed terminated.

(b) If you appeal the detention order, but do not request an informal hearing, the presiding officer must issue a decision on the appeal confirming or revoking the detention within 5 calendar days after the date the appeal is filed. If the presiding officer fails to confirm or terminate the detention order during such 5-calendar day period, the detention order is deemed terminated.

(c) If you appeal the detention order and request an informal hearing and your hearing request is denied, the presiding officer must issue a decision on the appeal confirming

or revoking the detention within 5 calendar days after the date the appeal is filed. If the presiding officer fails to confirm or terminate the detention order during such 5-calendar day period, the detention order is deemed terminated.

(d) If the presiding officer confirms a detention order, the article of food continues to be detained until we terminate the detention under § 1.384 or the detention period expires under § 1.379, whichever occurs first.

(e) If the presiding officer terminates a detention order, or the detention period expires, FDA must terminate the detention order as specified under § 1.384.

(f) Confirmation of a detention order by the presiding officer is considered a final agency action for purposes of 5 U.S.C. 702.

§ 1.406 How will FDA handle classified information in an informal hearing?

Where the credible evidence or information supporting the detention order is classified under the applicable Executive order as requiring protection from unauthorized disclosure in the interest of national security ("classified information"), FDA will not provide you with this information. The presiding officer will give you notice of the general nature of the information and an opportunity to offer opposing evidence or information, if he or she may do so consistently with

safeguarding the information and its source. If classified information was used to support the detention, then any confirmation of such detention will state whether it is based in whole or in part on that classified information.

PART 10--ADMINISTRATIVE PRACTICES AND PROCEDURES

3. The authority citation for 21 CFR part 10 continues to read as follows:

AUTHORITY: 5 U.S.C. 551-558, 701-706; 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

4. Section 10.45 is amended by revising paragraph (d) introductory to read as follows:

§ 10.45 Court review of final administrative action; exhaustion of administrative remedies.

* * * * *

(d) Unless otherwise provided, the Commissioner's final decision constitutes final agency action (reviewable in the courts under 5 U.S.C. 701 et seq. and, where appropriate, 28 U.S.C. 2201) on a petition submitted under § 10.25(a), on a petition for reconsideration submitted under § 10.33, on a petition for stay of action submitted under § 10.35, on an advisory opinion issued under § 10.85, on a matter involving administrative action which is the subject of an opportunity for a hearing under § 16.1(b) of this chapter, or on the issuance of

a final regulation published in accordance with § 10.40, except that the agency's response to a petition filed under section 505(j)(2)(C) of the act (21 U.S.C. 355(j)(2)(C)) and § 314.93 of this chapter will not constitute final agency action until any petition for reconsideration submitted by the petitioner is acted on by the Commissioner.

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PART 16--REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

5. The authority citation for 21 CFR part 16 continues to read as follows:

AUTHORITY: 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201-262, 263b, 364.

6. Section 16.1 is amended in paragraph (b)(1) by adding an entry in alphanumerical order as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(1) * * *

Section 304(h) of the act relating to the administrative detention of food for human or animal consumption (see part 1, subpart k of this chapter).

* * * * *

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Dated: May 13, 2004.

May 13, 2004.

Lester M Crawford

Lester M. Crawford,
Acting Commissioner of Food and Drugs.

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Dated: MAY 25 2004.

May 25, 2004.

Tommy G. Thompson,
Secretary of Health and Human Services.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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